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| 10/519,863 | 12/29/2004 | Robert Allan Phillips | 14450.8USWO | 9292 |

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| EXAMINER | |
|---|---|
| SCHAETZLE, KENNEDY | |

| ART UNIT | PAPER NUMBER |
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| 3766 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/519,863 | PHILLIPS, ROBERT ALLAN | |
| | Examiner | Art Unit | |
| | Kennedy J. Schaetzle | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 3-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/5/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koestner (Pat. No. 5,139,020) in view of Devereux et al. (article entitled: "Relations of Doppler Stroke Volume and its Components to Left Ventricular Stroke Volume in Normotensive and Hypertensive American Indians").

Regarding claims 1 and 5, Koestner et al. do not utilize a transcutaneous CW Doppler signal and thus do not disclose monitoring means that are noninvasive. Koestner et al., however, do disclose that it is known in the art to use noninvasive Doppler to measure blood flow parameters, but that prior artisans have not used the signal to control cardiac functions such as pacing (col. 5, lines 31-43). While Koestner et al. go on to disclose an invasive CW Doppler monitor, those of ordinary skill in the art given the disclosure of Koestner et al. that noninvasive measurements of cardiac output can be made, would have had a reasonable expectation that tuning a pacer with a noninvasive Doppler monitoring means would have met with success. Anyone looking to limit the complexity of the implant, or looking to expand the signal processing capabilities and speed beyond that capable with the limited processing power of the pacer and concomitantly reduce implant size and energy consumption, would have

seen the obviousness of trying the tuning procedure with a noninvasive monitoring means.

Regarding the obtainment of a velocity time integral, Koestner discloses that cardiac output and stroke volume may be derived from the product of the time average mean velocity and estimated cross-sectional area. The relationship between blood velocity and stroke volume is old and well-known. Devereux et al., for example, teach that the velocity time integral of blood flow from Doppler echocardiography has been proposed to measure cardiac pump performance such as stroke volume (see abstract). Given Koestner's suggestion to enhance cardiac pump performance by adjusting pacer operation in accordance with cardiac output and stroke volume, and the known relationship between stroke volume and velocity time integral measurements as discussed by Devereux et al., those of ordinary skill in the cardiac treatment arts would have found it obvious to process the measured signal to obtain a velocity time integral useful in calculating stroke volume.

Regarding claim 3, because the system of Koestner et al. is implanted and uses feedback of flow output to automatically adjust the timing of pacing events, it can be said that the device necessarily performs the method of claim 1 under a variety of different operating conditions due to the natural activity of the implant patient over the course of the day (which for all intensive purposes for a typical human would include walking and/or running). In any event and accounting for non-invasive systems, Koestner et al. teach that cardiac output naturally varies with exercise (col. 14, lines 37-68). Clearly a pacer patient with a rate responsive device that is exercising (e.g.,

walking or running) requires the device to accurately account for the increased activity by adjusting the pacing rate to provide the necessary cardiac output –just as a healthy heart would. It is also well known that when fitting a pacer device to a patient, the effectiveness of the pacer in accounting for physical activity is typically tested by requiring the patient to perform exercise. It would in fact be unthinkable to implant a pacer without testing the response of the implant to induced cardiovascular stress. Those of ordinary skill in the art recognizing the relationship between exercise and cardiac output and recognizing the importance of testing the pacer's response to a variety of expected conditions, would have seen the obviousness of tuning the pacer to account for exercise such as walking and/or running.

Regarding claim 4, because the system of Koestner et al. is implanted and uses feedback of flow output to automatically adjust the timing of pacing events, it can be said that the device necessarily performs the method of claim 1 under a variety of different operating conditions including those associated with drug therapy. In other words, if a drug were to have an affect on the pacer implant patient's cardiac output, the pacer system of Koestner et al. would automatically and inherently take this into account and attempt to remedy a lower output, for example, by increasing the pacing rate. In any event and accounting for non-invasive systems, those of ordinary skill in the art recognizing that various drugs may affect cardiac output and/or blood flow, would have readily understood the importance of testing a pacing device that is designed to affect changes in cardiac output by testing the device in the presence of cardiac output affecting drugs expected to be used by the patient in order to avoid unintended or

potentially dangerous consequences. To therefore test the pacer under a number of different pharmalogical conditions for the patient would have been considered obvious by those of ordinary skill in the medical arts.

***Response to Arguments***

3. Applicant's arguments filed August 5, 2008 have been fully considered but they are not persuasive.

The applicant's argument that Koestner does not disclose the use of a transcutaneous signal "directed at the heart" is not agreed with. As stated above, Koestner discloses that prior artisans have used transcutaneous Doppler to measure blood flow and determine cardiac output and stroke volume (see col. 5, lines 31-44). The term "directed at the heart" has not been defined by the applicant with such specificity as to limit the application of prior art devices/methods that measure flow velocity in the aorta or pulmonary artery. One of ordinary reason in the art would have considered the term "directed at the heart" to include such cardiac locations. Furthermore, regarding the obtainment of a signal indicative of intra-cardiac blood flow velocity, those of ordinary skill in the art would have considered the signals discussed in Koestner to be in the very least *indicative* of intra-cardiac blood flow because the flow of blood in the aorta or pulmonary artery is related to the flow of blood within the heart. The applicant's own specification teaches that aortic and pulmonary signals may be suitably employed in the operation of the device (see for example page 3, lines 31 and 32, as well as the incorporation by reference to WO 99/66835). The exact choice of

measurement location from amongst suitable locations would therefore appear to be a matter of obvious design in the practice of the invention.

Regarding the suggestion by the applicant that Koestner teaches away from using non-invasive techniques, the fact that Koestner discloses that non-invasive Doppler measurement techniques are known but only describes in detail an invasive technique does not equate to teaching away from using non-invasive techniques. As stated in section 2123 of the MPEP: "...a known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). The examiner further provided reasoning as to why one might opt for a non-invasive technique over an invasive one. The choice would have therefore been considered a matter of obvious design based upon the application at hand.

***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy J. Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766

KJS
December 4, 2008